

Application No.: 10/506,577
Amendment Date: 14 May 2007
Reply to Office Action of: 21 February 2007

AMENDMENTS TO THE DRAWINGS:

The attached sheet of drawings includes changes to Figure 1B. This sheet, which includes Figure 1A, replaces the original sheet including Figure 1A. In Figure 1B, previously omitted label "FIG. 1B" has been added.

The attached sheet of drawings also includes omitted Figure 9A and 9B. The Figure legend for Figure 9A and 9B is in the paragraph beginning on line 25, page 6, and the data that was used to make Figures 9A and 9B is in the paragraph beginning on line 17, page 24.

Attachment:

Replacement Sheet for Figures 1A and 1B

Annotated Sheet Showing Changes to the Replacement Sheet for Figures 1A and 1B.

New sheet for Figures 9A and 9B.

REMARKS/ARGUMENTS

Claims 1-12 are pending, no claims have been allowed.

Several paragraphs in the specification have been amended to correct errors with respect to the citation of particular Figures.

Claim 1 was amended to correct a typographical error.

Claim 11 was amended to clarify that in the claimed method, "a decrease in the level of AGRP is indicative of the effectiveness of the regime."

I. Corrected Drawings

Figure 1 was objected to because while Figure 1A was labeled, Figure 1 B was not labeled. Figure 1 has been corrected to include a label for Figure 1B. A replacement sheet for Figure 1 is provided.

Figure 9 was objected to because the application refers to Figures 9A and 9B but the Figures were not included with the drawings. The applicants provide a new sheet containing Figures 9A and 9B. The new sheet for Figures 9A and 9B does not add new matter to the application because the figure legend for Figures 9A and 9B is in the paragraph beginning on line 25, page 6, and the data used to make Figures 9A and 9B is in the paragraph beginning on line 17, page 24. The new sheet containing Figures 9A and 9B is not believed to introduce new matter into the application.

In light of the above, it is believed the objections to the drawings has been satisfactorily addressed. Reconsideration of the objections is requested.

II. Claims 1-5 and 9-12 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Katsuki et al. in view of Shimokawa et al.

The prior art is not believed to render Claims 1-5 and 9-12 obvious. The claimed invention is a method for determining the efficacy of a compound given to a subject for treatment of obesity by measuring the levels of AGRP in the plasma of the subject before and after administering the compound to the subject wherein efficacy of the compound for treating obesity is indicated when there is a decrease in AGRP in the plasma of the subject after administration of the compound. The assay is further limited to compounds that are appetite suppressants that do not stimulate the release of serotonin.

Katsuki teaches that plasma levels of AGRP in obese men are elevated over plasma levels of AGRP in non-obese men and that these levels are correlated with various

parameters of obesity. However, Katsuki further states that although the correlation does not prove causation, the results suggest that peripheral AGRP may play a role in the pathogenesis of obesity. Katsuki does not teach that treatments for obesity will or might result in a decrease in AGRP levels. Katsuki does not suggest that the efficacy of treatments for obesity can be determined by measuring the levels of AGRP in the serum of a subject before and after administering a compound to the subject.

Shimokawa teaches that the fatty acid synthase inhibitor C75 causes a decrease in food intake and a decrease in body weight. Shimokawa showed that C75 prevented fasting-induced upregulation of mRNA encoding AGRP in the hypothalamus obtained from obese mice 24 hours post-administration of C75 (Shimokawa, Fig. 3C) and also showed that over a six hour time period C75 caused a significant increase in the levels of mRNA encoding AGRP in the hypothalamus (Shimokawa, Fig. 5a). It is important to note that Shimokawa is measuring mRNA levels in the hypothalamus whereas the applicants are measuring AGRP protein levels in plasma. While Shimokawa shows that C75 affects expression of mRNA encoding AGRP in the hypothalamus, they do not show that the expression correlates in any way with AGRP levels in plasma nor do they show that C75 causes a decrease in mRNA encoding AGRP. Finally, Shimokawa does not suggest that efficacy of appetite-suppressing compounds that do not stimulate release of serotonin for treatment of obesity can be determined using the claimed method wherein a decrease in AGRP levels in serum is indicative that the compound is efficacious for treating obesity.

Katsuki in view of Shimokawa is not likely to lead one of ordinary skill in the art to the applicants' claim invention because while Katsuki teaches that obese men have higher plasma levels of AGRP, the results of Shimokawa do not suggest that measuring serum protein levels of AGRP would provide an effective way to monitor efficacy of obesity treatments, particularly when Shimokawa shows that after six hours treatment with C75 there was an increase in mRNA encoding AGRP (Shimikowa, Fig. 5a). Thus, one of ordinary skill in the art would have to speculate that despite the results in Shimokowa showing an increase in mRNA expression, one could indeed measure the efficacy of obesity treatments by monitoring a decrease in AGRP protein levels in the serum of a subject following administration of the treatment to the subject as claimed.

In light of the above, Claims 1-5 and 9-12 are believed to be patentable over the prior art. Reconsideration of the rejection is requested.

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III. Claims 6-8 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Katsuki et al. in view of Shimokawa et al. further in view of Rosen et al.

In light of the discussion above, the further addition of Rosen, which relates to methods for measuring protein levels of cytokines using an ELISA method, a radio-ligand binding method, and a liquid chromatography method, does not render the Claims 6-8 obvious. The addition of Rosen to the rejection appears to have been made to provide a mechanism for Katsuki in view of Shimokawa to be applied to Claims 6-8. However, in light of the discussion above concerning Katsuki in view of Shimokawa, Claims 6-8 are believed to be unobvious over Katsuki in view of Shimokawa and further in view of Rosen. Reconsideration of the rejection is requested.

In view of the foregoing amendments and remarks, it is believed that the grounds of rejections have been overcome and that the claims are in proper condition for allowance. Accordingly, Applicants respectfully request that all of the rejections be withdrawn and a Notice of Allowance be forwarded to the Applicants. The Examiner is invited to contact Applicants' Attorney at the telephone number given below, if such would expedite the allowance of this application.

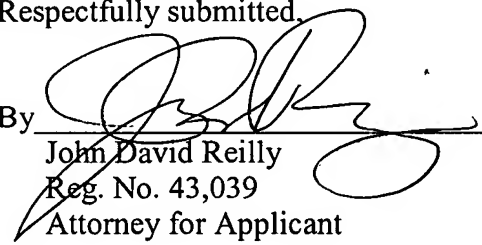
Favorable action is earnestly solicited.

CONDITIONAL PETITION

Applicant hereby makes a Conditional Petition for any relief available to correct any defect in connection with this filing, or any defect remaining in this application after this filing. The Commissioner is authorized to charge deposit account 13-2755 for the petition fee and any other fee(s) required to effect this Conditional Petition.

Respectfully submitted,

By


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Appendix: Replacement Sheet for Figures 1A and 1B
Annotated Replacement Sheet for Figures 1A and 1B
New sheet for Figures 9A and 9B